FDA News

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Media Inquiries:
Karen Riley, 301-827-6244
Consumer Inquiries:
888-INFO-FDA

FDA Receives New Data on Risks of Anemia Drugs

Consistent With Previous Data on Tumor Growth and Death

The U.S. Food and Drug Administration (FDA) is reviewing new data from two studies that provide further evidence of the risks of anemia drugs known as erythropoiesis-stimulating agents, or ESAs. The studies show that patients with breast or advanced cervical cancers who received ESAs to treat anemia caused by chemotherapy died sooner or had more rapid tumor growth than similar patients who didn't receive the anemia drug.

These two studies were not among the six studies that were described in revised labeling approved by FDA Nov. 8, 2007, which strengthened warnings about ESAs in cancer patients.

Taken together, all eight studies show more rapid tumor growth or shortened survival when patients with breast, non-small cell lung, head and neck, lymphoid or cervical cancers received ESAs compared to patients who did not receive this treatment. In all of these recent studies, ESAs were administered in an attempt to achieve a hemoglobin level of 12 grams per deciliter (g/dL) or greater, although many patients did not reach that level.

FDA plans to discuss this new data and revisit the risks and benefits of using ESAs in patients with chemotherapy-induced anemia at a public advisory committee meeting in the next few months.

"This new information further underscores the safety concerns regarding the use of ESAs in patients with cancer, which FDA addressed in previous communications," said Janet Woodcock, M.D., FDA's deputy commissioner for scientific and medical programs, chief medical officer, and acting director of the Center for Drug Evaluation and Research.

"FDA is reviewing these data and may take additional action. In the meantime, FDA recommends that health care providers review the risks and benefits of ESAs outlined in the product label and discuss this information with their patients."

ESAs are a bioengineered version of a natural protein made in the kidney that stimulates the bone marrow to produce more red blood cells.

Physicians determine whether a patient is anemic and decide on ESA dosing by measuring how much of the protein known as hemoglobin is present in a patient's red blood cells, typically expressed in grams per deciliter.

FDA-approved uses of ESAs are for the treatment of anemia in patients with chronic kidney failure; for cancer patients whose anemia is caused by chemotherapy; and for those infected with the human immunodeficiency virus (HIV) whose anemia is caused by the HIV drug AZT (zidovudine). ESAs are also approved to reduce the number of transfusions during and after major surgery.

On Nov. 30, Amgen, manufacturer of the three ESAs -- Aranesp, Epogen, and Procrit -- provided FDA with information from the 733-patient PREPARE study of women who received chemotherapy before undergoing surgery for breast cancer. After three years, 14 percent of the patients who received Aranesp to treat their anemia had died, compared to 9.8 percent who did not receive the drug. Tumor growth was also faster in patients receiving Aranesp.

On Dec. 4, Amgen informed FDA of the results of a study by the National Cancer Institute's Gynecologic Oncology Group of patients receiving chemotherapy and radiation for advanced cervical cancer. The patients were administered either Procrit to maintain hemoglobin levels above 12 g/dL or blood transfusions as needed. After three years, 66 percent of the patients who did not take Procrit were alive and free of cancer growth compared to 58 percent who had received the drug.

FDA approved revised boxed warnings and other safety-related product labeling changes for ESAs in

November and March 2007. Safety concerns regarding ESAs were discussed during advisory committee meetings in 2004 and 2007 and labeling was revised in 1997, 2004 and 2005 to reflect new safety information

This communication is in keeping with FDA's commitment to inform the public about its ongoing safety reviews. FDA is committed to strengthening the science that supports medical product safety at every stage of the product life cycle from pre-market testing and development through post-market surveillance and risk management.

Amgen is based in Thousand Oaks, Calif. Procrit is marketed and distributed by Ortho Biotech LP of Bridgewater, N.J, a subsidiary of Johnson & Johnson.

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Communication about an Ongoing Safety Review

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